K102313

6.0 Summary of Safety and Effectiveness

SEP 30 2010

This 510(k) Summary of Safety and Effectiveness is provided in accordance with 21 CFR 807.92.

Date of preparation: August 19, 2010

Submitter information:

Calypso Medical Technologies, Inc.
2101 Fourth Avenue, Suite 500
Seattle, WA 98121

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Contact: Sue Ridge
Regulatory Affairs/Quality Systems Manager

Device trade name: Calypso® System with Dynamic Edge™ Gating

Common name: Patient localization system

Regulation name: Medical charged-particle radiation therapy system

Regulation: CFR 892.5050
Class II
Product code – LHN, IYE

Predicate devices: Calypso® 4D Localization System
(K060906; K080726)

Indications for Use:
The Calypso 4D Localization System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The Calypso System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon transponders.

Beacon transponders are indicated for use to radiographically and electromagnetically mark soft tissue for future therapeutic procedures.

Permanent Beacon transponders are indicated for permanent implantation in the prostate and the peri-prostatic tissue (i.e., prostatic bed).

Device Description:
The Calypso System with the Dynamic Edge™ Gating modification enables the Calypso System to interface with radiation therapy systems configured with gating capabilities via an interface to external systems. This modification includes updated computer software and hardware.

All other features of the Calypso System remain as cleared by K060906 and K080726.

Summary of Technological Characteristics:
As described in K060906 and K080726, the Calypso System with the gating interface option utilizes non-ionizing electromagnetic and optical technology to provide accurate, objective, and continuous localization of a treatment target.

Summary of Performance Testing:
The Calypso System has undergone performance testing, including design verification and validation, software verification and validation, electromagnetic compatibility as well as other assessments to demonstrate that the system meets its intended use, is safe and effective, and performs comparably to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 21 2010

Mr. Ed Vertatschitsch
Chief Executive Officer
Calypso Medical Technologies, Inc.
2101 4th Avenue, Suite 500
SEATTLE WA 98121

Re: K102373
Trade/Device Name: Calypso 4D Localization System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: September 22, 2010
Received: September 23, 2010

Dear Mr. Vertatschitsch:

This letter corrects our substantially equivalent letter of September 30, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

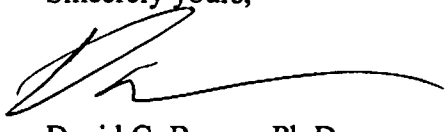
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

5.0 Indications for Use Statement

SEP 3 0 2010

510(k) Number (if known): K102373

Device Name: Calypso 4D Localization System

Indication for Use:

The Calypso 4D Localization System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The Calypso System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon transponders.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-the-counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102373